K091582

## 510(k) Summary

DEC - 4 2009

| | |
|---|---|
| **Submitter:** | Medtronic Vascular<br>37A Cherry Hill Drive |
| **Contact Person:** | Colleen Mullins<br>Senior Regulatory Affairs Specialist<br>Phone: (978) 739-3267<br>Fax: (978) 739-7380 |
| **Alternate Contact** | Fred Boucher<br>Director of Regulatory Affairs<br>Phone: (978) 739-3116<br>Fax: (978) 739-7380 |
| **Date Prepared:** | May 29, 2009 |
| **Trade Name:** | GTX Guidewire |
| **Common Name:** | PTCA Guidewire |
| **Classification Name:** | Wire, Guide, Cardiovascular |
| **Predicate Devices:** | GT2 Fusion Guidewire (K001969)<br>Radius PTCA Guidewire (K970466) |
| **Device Description:** | The Medtronic GTX Guidewire are steerable guide wires available in a variety of stiffnesses with available hydrophilic and hydrophobic coatings, which allow for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature. |
| **Statement of Intended Use:** | Medtronic GTX guide wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. Medtronic guide wires are not intended for use in the cerebral vasculature. Medtronic steerable exchange wires are used to facilitate the substitution of one diagnostic or interventional device for another. |
| **Summary of Technological Characteristics:** | The Medtronic Vascular GTX Guidewire consists of a corewire covered with spring coils and terminated in a hemispherical tip, which impart various characteristics to the |

| | |
|---|---|
| | distal tip of the wire, such as tip stiffness. Wire coatings provide sufficient lubricity to reach and cross target lesions. Markers on the proximal portion of the corewire aid in gauging guide wire position relative to the guiding catheter tip. |
| **Summary of Non-clinical Data:** | The Medtronic GTX Gudiewire has successfully passed all verification testing. |
| **Summary of Clinical Data:** | No clinical investigation has been performed for this device. |
| **Conclusion from Data:** | Medtronic has demonstrated that the GTX Guidewire is substantially equivalent to the predicate devices based on its indications for use and fundamental scientific technology. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC - 4 2009

Medtronic Vascular
c/o Ms. Colleen Mullins
Senior Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, MA 01923

Re: K091582
Trade/Device Name: GTX Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: October 30, 2009
Received: November 2, 2009

Dear Ms. Mullins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number K091582:

Device Name: GTX Guidewire

Indications for Use:

Medtronic GTX guide wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. Medtronic guide wires are not intended for use in the cerebral vasculature. Medtronic steerable exchange wires are used to facilitate the substitution of one diagnostic or interventional device for another.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091582